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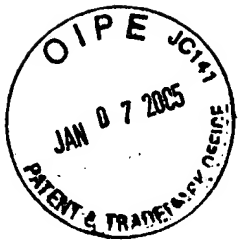

Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPLICANT:	Christopher T. Boyle	CUSTOMER NO. 29,335
SERIAL NO.:	09/716,146	EXAMINER: Cheryl L. Miller
FILING DATE:	11/17/00	A.U.: 3738
TITLE:	DEVICE FOR IN VIVO DELIVERY OF BIOACTIVE AGENTS AND METHOD OF MANUFACTURE THEREOF	

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Lori Dunham

SUBMISSION OF APPELLANT'S BRIEF ON APPEAL

Dear Sir:

Appellant submits herewith Appellant's Brief on Appeal. The Commissioner is authorized to deducted the required fee for filing an Appeal Brief in the amount of $500.00 from Deposit Account 18-2000, of which the undersigned is an authorized user. Appellant has previously filed a Request for One Month Extension for filing its Appeal Brief and paid the appropriate fee therefor. Accordingly, Appellant does not believe any additional fees are due with the Appeal Brief, however,

the Commission is authorized to charge any additional fees regarding this filing, and/or credit any overpayment, to deposit account No. 18-2000. A duplicate copy of this request is enclosed.

Respectfully submitted,

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Docket No. 6006-018

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE
BOARD OF PATENT APPEALS AND INTERFERENCES

In re: Application of Christopher T. Boyle

Serial No.: 09/716,146

Filing Date: November 17, 2000

Title: DEVICE FOR IN VIVO DELIVERY OF BIOACTIVE AGENTS AND METHOD OF MANURACTURE THEREOF

APPELLANT'S BRIEF ON APPEAL

1. Real Party in Interest.

The real party in interest for this patent application is Advanced Bio Prosthetic Surfaces, L.L.C., the assignee of the application.

2. Related Appeals and Interferences.

No related appeals or interferences exist with reference to the above referenced patent application.

3. Status of Claims.

Claims 16, 20, 26-28 stand finally rejected under 35 U.S.C. §102(e) as being anticipated by Brown, et al., U.S. Patent No. 6,071,305. The rejection of each claim is under appeal.

4. Statement of Amendments.

No amendments have been filed after the issuance of the final rejection.

5. Summary of the Claimed Subject Matter.

Claim 16 is the sole independent claim pending in the application. Antecedent support for each element in Claim 16 is noted in the parentheses following each claim element:

An endoluminal stent for delivering a bioactive agent to a situs in a body, comprising:

a plurality of structural elements (Page 4, lines 1-2) forming a radially expandable cylindrical member (Page 6, lines 26-30; Page 7, lines 4-6) the plurality of structural elements having a wall thickness (See, e.g., Figures 6-10; Page 10, line 11; Page 20-23); wherein the structural elements are fabricated of a metal (Page 8, lines 23-26) and comprised of a first region comprising a base layer (Page 11, lines 8-11) and a second region comprising a second layer covering the base layer (Page 11, lines 11-12), the second region further comprising a layer of void space intermediate the base and second layers and enclosed therebetween (Page 11, lines 12-13);

a plurality of pores passing through at least one of the base and second layers and communicating with the void space (Page 7, line 3 – Page 8, line 16; Page 10, lines 8-15; Page 11, lines 12-13); and

at least one bioactive agent retained within the void space and elutable through the plurality of pores (Page 8, lines 4-16).

6. Grounds of Rejection to be Reviewed on Appeal.

Rejection of Claims 16, 20, 26-28 Claims 16, 20, 26-28 under 35 U.S.C. §102(e) as being anticipated by Brown, et al., U.S. Patent No. 6,071,305.

The Examiner finally rejected the subject claims, arguing, with respect to Claim 16, that the references discloses an endoluminal stent (11, 40') comprising a plurality of structural elements (element 12, Figure 1) forming a radially expandable cylindrical member, the structural elements are fabricated from metal (Col. 7, lines 12-19) having a wall thickness, i.e., the thickness of wire/fiber/filaments, shown in Fig. 5-9 and 12, wherein the structural elements are comprised of a first region comprising a base layer and a second region comprising a second layer covering the base layer, the second region further comprising a layer of void space intermediate the base and second layers and enclosed therebetween and a plurality of pores passing through at least one of the base and second layers and communicating with the void space and at least one bioactive agent (23) retained within the void space (20 or channel) and elutable through the plurality of pores (22, 28, 54).

In construing the structural elements, the Examiner has maintained that the stent may consist of a mesh or roving wire stent, with each elongated member 12 being a filament or fiber which forms a mesh stent, as disclosed in Col. 7, lines 34-40. Moreover, the Examiner points out that while Brown shows a helical stent made of one structural element in Figure 1, the reference also discloses use of a stent with multiple structural elements, wire, fibers or filaments in Col. 7, lines 12-19.

In construing the claimed base layer, the Examiner argues that the Brown reference teaches a corresponding structure being the layer on the inside of the vessel as seen in cross section, for example, in Figs. 6 or 8. The Examiner further argues that using Brown's disclosed square cross-section, one side of the square is the base layer; and bottom layer of 40'' in Fig. 12.

In construing the claimed second region comprising a second layer, the Examiner alleges that the Brown reference teaches a corresponding element being the layer touching the vessel as seen in cross section, for example, Fig. 6 or 8. Again the Examiner further argues that using Brown's disclosed square cross-section, the opposing side is the second layer, and top layer 40; seen in Fig. 12, which covers the base layer.

With regard to Claim 20, the Examiner has argued that the Brown reference discloses a degradable plug within the plurality of pores based upon the matrix 27 extending into a pore or membrane 34, 50. Col. 8, lines 62-65, Col 9, lines 12-21.

With regard to Claim 26, the Examiner argues that the Brown reference teaches a stent (10, 40") having structural elements (member 12 in Figs 1-10, or member shown in Fig. 12) which comprises a material selected from the group claimed (Col. 7, lines 12-19).

Claim 27 stands rejected over the Brown reference, which the Examiner alleges teaches a bioactive or active agent (23) selected from the group claimed (Col. 5, liens 1-27).

Finally, Claim 28 stands rejected over the Brown reference, which the Examiner alleges discloses a void space (20 or channel in Fig. 12) comprising a plurality of independent internal cavities along the length of the structural elements (cavity 20 may be intermittent, Col. 5, lines 52-55).

7. Argument

Claims 16, 20 and 26-28 are directed to a specific embodiment of the invention described in the specification as originally filed at Page 8, lines 2-13, which describes the embodiment with reference to the a vacuum deposition process for fabricating the device as follows:

> "Where an implantable device is to be formed from non-preexisting structural elements, vacuum deposition techniques may be employed to form the implantable structural body, such as sputtering, reactive ion etching, chemical vapor deposition, plasma vapor deposition, or the like, as are known in the microelectronics fabrication arts and are more fully described in co-pending, commonly assigned U.S. Patent Application Serial No. 09/443,929, filed November 19, 1999, which is hereby incorporated by reference. ***Because, the internal cavities and openings must be formed during deposition, the vacuum deposition techniques must be modified to deposit requisite patterns of sacrificial material to form the regions of the internal cavities and openings, over a base layer of structural material, then depositing a second layer of structural material over the sacrificial material and the base layer. The sacrificial material may then be removed, such as by etching, to leave the internal cavities and plurality of openings formed within the deposited bulk material.***" [Emphasis added]

Rather than focusing on Applicant's invention, as claimed, the Examiner's rejection, instead, focuses on subject matter more closely related to other, unclaimed, embodiments of Applicant's invention described in the specification. ~

The propriety of the Examiner's rejection of each of the appealed claims as being anticipated under 35 U.S.C. §102(e), lies upon the meaning of the word "layer." Independent Claim 16 requires that the "...structural elements are fabricated of a metal and comprised of a first region comprising a base layer and a second region comprising a second layer covering the base layer..." Thus, there are two claimed elements, a "base layer" and a "second layer" covering the base layer.

The crux of the Examiner's anticipatory rejection rests with the interpretation of a coherent tubular structure having a generally square transverse cross-sectional shape as inherently including a "first layer" and a "second layer" covering the first layer. The Examiner has unequivocally held that if one segments the square transverse cross-

sectional shape into a two sides, such segmented square tubular member has a "first layer" and a "second layer" covering the first layer.

Such deconstruction of the disclosure in Brown is wholly without suggestion in the reference itself. Furthermore, the Examiner has failed to provide any rationale as to why one would segment a coherent tubular structure into two segments to derive the "first layer" and the "second layer." Moreover, the Examiner has failed to consider how such a modification would alter the device taught by the reference. Finally, such deconstruction and reconstruction of the disclosed device is improper to support a rejection under 35 U.S.C. §102(e).

The Meaning of the Term "Layer"

It is virtually axiomatic that words in a claim are given their ordinary and accustomed meaning unless it appears that the inventor used them differently. *Envirotech Corp. v. Al George, Inc.* 730 F.2d 753, 221 USPQ 473 (Fed. Cir. 1984).

In determining whether the inventor used a term differently than its ordinary and accustomed meaning, one turns to the specification and prosecution history. *ZMI Corp. v. Cardiac Resuscitator Corp,* 844 F.2d 1576, 6 USPQ2d 1557 (Fed. Cir. 1988).

In the present case, the primary point of departure between the Examiner's citation of the Brown reference under 35 U.S.C. §102(e) and the invention claimed in each of Claims 16, 20, 26-28 lies in the proper construction of the claim term "layer." Each of Claims 16, 20, 26-28 requires that the claimed device include a "base layer" and a "second layer" covering the first layer. Hence, each of the claims requires two separate and discrete elements.

Nowhere in Applicant's specification or in the prosecution history of the application, to date, does Applicant expressly or impliedly define the term "layer." Hence, both the Examiner and the Board of Patent Appeals and Interferences are constrained to accept the ordinary and usual meaning of that term. In order to shed light on the ordinary meaning of the term, we refer to The American Heritage Stedman's Medical Dictionary Copyright 2002, 2001, 1995 by Houghton Mifflin Company which defines the noun "layer" as "a single thickness of a material covering a surface or forming an overlying part or segment."

Thus, using the plain meaning of the term "layer" the claim elements "base layer" and "second layer" covering the base layer, as used in each of the claims, must be construed to require two different elements. The claimed "base layer" is wholly consistent with the dictionary definition of "layer" as being "a single thickness of a material covering a surface" while the claimed "second layer" is positively recited in the Claims as covering the first layer, i.e., "forming an overlying part;" consistent with the dictionary definition.

The Examiner's Rejection Under 35 U.S.C. §102(e) is Legally Improper

In order to establish proper anticipation under 35 U.S.C. §102, each and every element of the claimed invention must be disclosed in a single prior art reference. *In re Spada*, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990). The claimed elements must either be inherent or disclosed expressly in the single prior art reference, *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 7 USPQ2d 1057 (Fed. Cir. 1988), and must be arranged as in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989). The absence from the reference of any claimed element necessarily negates anticipation. *Kloster Speedsteel AB v. Crucible Inc.,* 793 F.2d 1565, 220 USPQ 81 (Fed. Cir. 1986).

In support of her anticipation rejection based upon the Brown reference, the Examiner is correct that Brown discloses an endoluminal stent (11, 40') comprising a plurality of structural elements (element 12, Figure 1) forming a radially expandable cylindrical member, the structural elements are fabricated from metal (Col. 7, lines 12-19) having a wall thickness, i.e., the thickness of wire/fiber/filaments, shown in Fig. 5-9 and 12, a void space and a plurality of pores passing through at least one of the base and second layers and communicating with the void space and at least one bioactive agent (23) retained within the void space (20 or channel) and elutable through the plurality of pores (22, 28, 54). The Examiner, however, is incorrect in her position that the Brown reference discloses structural elements that are comprised of a first region comprising a base layer and a second region comprising a second layer covering the base layer. And, since the Examiner is incorrect that the Brown reference discloses a base layer and a

second layer covering the base layer, the Examiner is similarly incorrect that the void space is intermediate the base and second layers and enclosed therebetween, as claimed.

While it is true that the transverse cross-sectional shape of the tubular member in Brown may be square (Col. 6, lines 1-5), merely configuring the shape of the tubular member to a square transverse cross-sectional shape does not impart a discrete base layer and second layer covering the base layer to the construct of the tubular member. In arguing that "one side of the square is the base layer; ... and a second region comprising a second layer ... covering the base layer..." the Examiner mythically dissects the unitary, coherent tubular member into two discrete layers. In order to derive the Examiner's dissection and reconstruction of the tubular member, it would be necessary that the tubular member be composed of either two discrete U-shaped members which are connected in some fashion at an interfacial region, or to have a single U-shaped member capped at an interfacial region with a planar member. In either case, the resulting "tubular member" necessarily would need to be constructed to two discrete and interfacing members or "layers" as claimed in each of Claims 16, 20 and 26-28.

Figures 6, 8 and 12, which the Examiner relies upon to support the anticipation rejection, fail to disclose two discrete layers consisting of a base layer and a second layer covering the base layer, with an intermediate void space enclosed therebetween. Figures 6, 8 and 12 are reproduced below in their original form and in a marked-up form illustrating the dissection and reconstruction advocated by the Examiner.

The embodiments represented in Figures 6 and 8 each represent a transverse cross-sectional view of a tubular member according to the Brown reference. In the embodiments illustrated in Figure 6 and 8, the depth of the cavity 20 is selected in based upon the need to have the stent 11' structurally support the lumen walls 24. (Col. 8, lines 15-19). With specific reference to Figures 6 and 12, this consideration results in a relatively thicker support region of the transverse cross-section of the tubular member and a drug-eluting region of the tubular member. With reference to Figure 8, however, the tubular member walls have a uniform transverse cross-sectional thickness. Thus, while it is true that the Brown reference discloses different functional regions of the tubular member, such different functional regions are not "layers" within the meaning of that term in the pending claims.

In Figure 6, below, in order to create a base layer and a second layer as proposed by the Examiner, the purported second layer, which the Examiner argues is that region adjacent the tissue 24, that region would have to be segregated from the remainder of the tube and rendered a discrete element with an interface between that region and the remaining portion of the tubular member. The bolded lines in the marked up Figure 6, below, illustrate the reconstruction suggested by the Examiner in which the region of the coherent tubular member adjacent the tissue 24 is a "base layer" while the region distant from the tissue 26 of the body lumen 24 is the second layer. However, this phantom "layer" is simply not supported expressly or impliedly by the Brown specification. Moreover, it is clear from the cross-hatching of tubular member 18 that the entire transverse cross-section is a single unitary, coherent tubular piece of material. No demarcation or segregation exists in Figure 6, or in the specification of the Brown reference, to suggest discrete elements constituting a base layer and a second layer covering the first layer.

Figure 6: Original

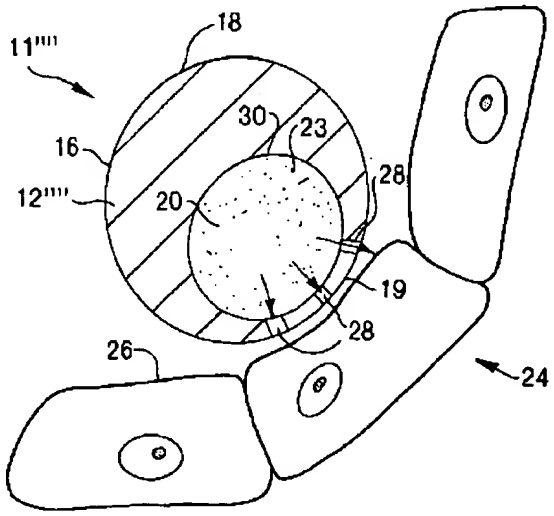


FIG. 6

Figure 6: Mark Up

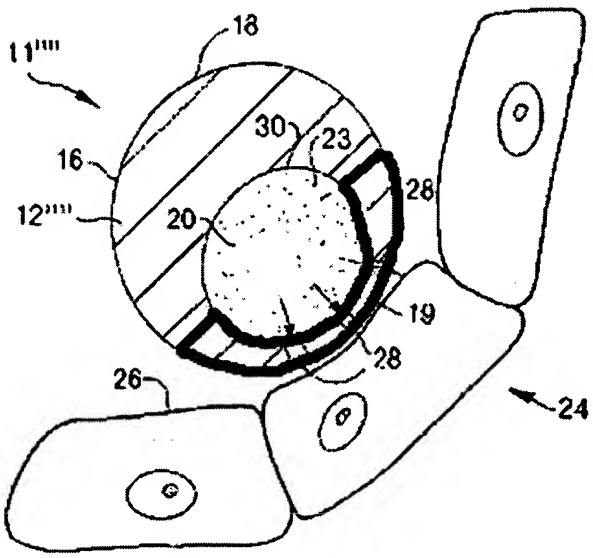


FIG. 6

Similarly, with reference to Figure 8, like the embodiment depicted in Figure 6, the cross-hatching in the Figure unequivocally conveys that the tubular member is a single unitary, coherent tubular piece of material, rather than one having a base layer and a second layer covering the base layer as claimed. The bolded lines in the marked up Figure 8, below, illustrate the reconstruction suggested by the Examiner in which the region of the coherent tubular member adjacent the tissue 24 is a "base layer" while the region distant from the tissue 26 of the body lumen 24 is the second layer. However, this phantom "layer" is simply not supported expressly or impliedly by the Brown specification. There is simply no demarcation or segregation in either Figure 8 or in the specification of the Brown reference to suggest the discrete elements of a base layer and a second layer covering the first layer.

Figure 8: Original

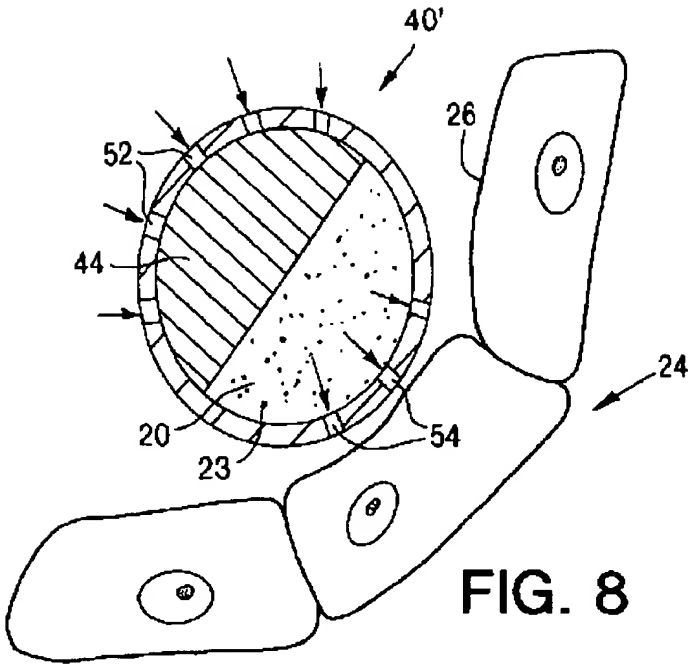


FIG. 8

Figure 8: Mark Up

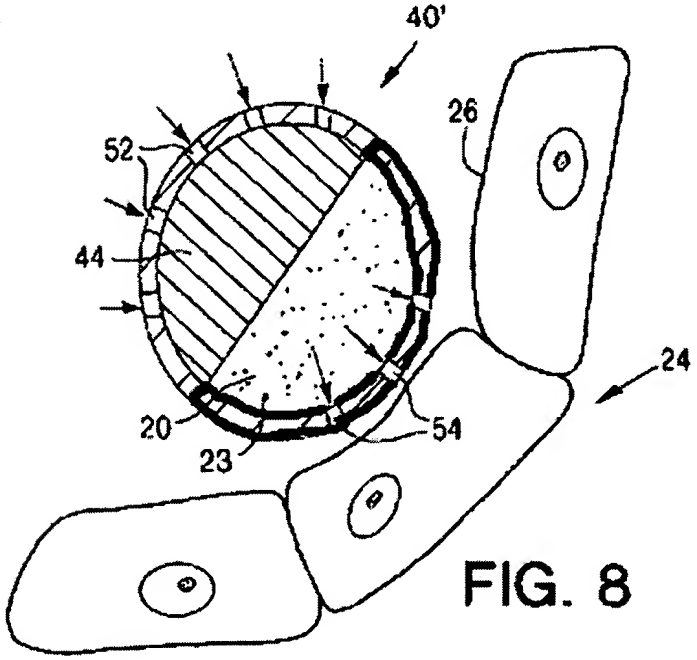


FIG. 8

Thus, with respect to the embodiments disclosed with reference to Figures 6 and 8, the Brown reference is legally inadequate as an anticipatory reference under 35 U.S.C. §102(e).

Turning to the Examiner's reliance upon the embodiment illustrated in Figure 12 of the Brown reference, the Examiner posits that in Figure 12, the bottom of layer 40" is the claimed base layer, while the top layer of 40" is the second layer covering the base layer, and that the claimed void space is anticipated by the channel occupied by 23 enclosed by walls of layer 40". A more detailed review of Figure 12, taken with the associated disclosure in the specification at Col. 11, lines 51-62, reveals that stent 40" is also a single, unitary, coherent member, having an interior cavity shaped like a channel within the stent body. The Examiner's dissection of Figure 12 in an attempt to match Applicant's claim elements of a "base layer" and a "second layer covering the first layer" is belied by the Figure itself, in which the purported "top layer of 40"" is really merely a portion of the stent body 40" and not a discrete layer. Similarly, the "bottom of layer 40"" is not a discrete layer, but is merely a lower region of the unitary stent body 40" which serves a structural function, as described in Col. 8, lines 14-19.

The marked up Figure 12 illustrates the modification to Figure 12 which would be required to fashion the "top layer of 40"" argued by the Examiner into a discrete "second layer covering the base layer" as claimed in Claim 16. As can be readily seen, a second discrete layer element having at least one opening passing therethrough would be required in order to anticipate the elements of Claim 16. This configuration is not expressly or impliedly disclosed in the Brown reference sufficient to support the Examiner's rejection under 35 U.S.C. §102(e).

Figure 12: Original

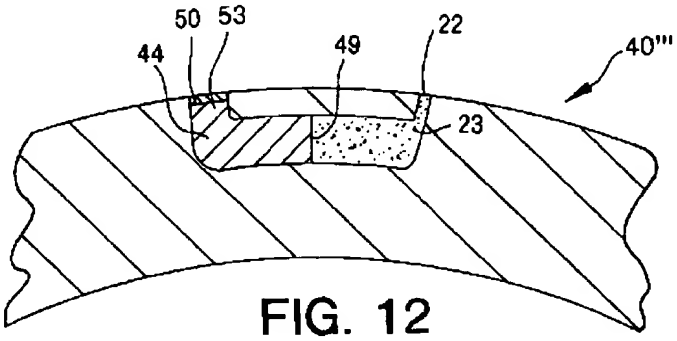


FIG. 12

Figure 12: Mark Up

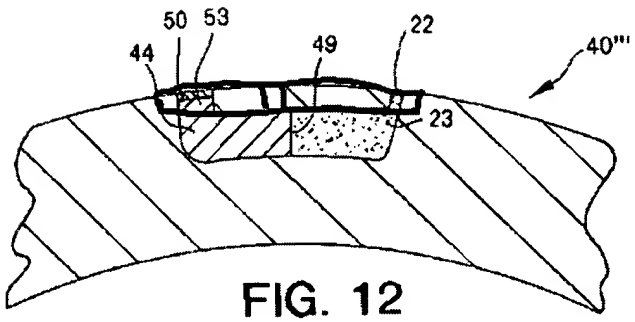


FIG. 12

Finally, that the Brown reference does not disclose a drug-eluting stent having structural members comprising a base layer and a second layer covering the base layer and a void space enclosed therebetween is further supported by the extensive disclosure of the manner in which the stent 111 in Brown is manufactured. See, e.g., Figs. 13-18 and Col. 12, line 1 to Col. 13, line 62. During manufacture of stent 111, a cylindrical tube 102 is employed as a starting material (Col. 12, lines 10-11). A helical groove 120 is formed in the exterior surface of tube 102 (Col. 12, lines 14-15), preferably by using a laser to define the groove to a depth which does not extend through the wall thickness of the tube 102 (Col. 12, lines 22-25). After the groove 120 has been formed, the tube 102 is coated with an active agent 123 which fills the groove 120 with the active agent 123 or a delivery matrix containing the active agent (Col .12, lines 36-45). The active agent 123 is then removed from the exterior surface of the tube 102, leaving the active agent 123 only in the groove 120 (Col. 12, lines 48-60). A plurality of slots 108 are then formed in the tube 102 and extend completely through the wall thickness of the tube 102 to permit diametric expansion of the stent 111 (Col. 12, line 61 to Col. 13, line 13). The slots 108 intersect the helical groove 120 and provide spaced apart groove portions (Col. 13, lines 14-43) containing the active agent.

Notably absent from the foregoing description of how the device in the Brown reference is manufactured is any mention of a second layer covering the base layer (presumably the stent 111), and the groove 120 (or void space as per the pending Claims), with the void space residing between the base layer (or stent 111) and the second layer. Rather, it is abundantly clear that the Brown reference unequivocally fails to disclose a second layer covering the base layer with the void space enclosed therebetween and fails

to disclose, in any manner whatsoever, that such a second layer is even contemplated during the manufacture process.

Accordingly, in the absence of the express or implicit disclosure in the Brown reference of the claimed elements of a "base layer," a "second layer covering the base layer," an "intermediate void space enclosed therebetween" the anticipation rejection under 35 U.S.C. 102(e) based upon the Brown reference is legally defective.

Claim 20 is Patentable over the Brown Reference Under 35 U.S.C. §102(e)

The Examiner has rejected claim 20 as being anticipated by the Brown reference arguing that the reference discloses a degradable plug residing within the plurality of pores, citing "matrix 27 extending into pore [sic] or membrane 35, 50 and referencing Col. 8, lines 62-65 and Col. 9, lines 12-21. Col. 8, lines 62-65, however, fails to teach that the biocompatible delivery matrix 27 resides within the pores. Rather, quite the opposite is the case, Brown expressly states that where employed (as it is not a necessary element, see, e.g., Col. 9, lines 6-9) the delivery matrix 27 resides within cavity 20 rather than within the pores 22. Moreover, even if one were to construe the delivery matrix 27 as residing within the pores 22, the delivery matrix is not a plug "to prohibit release of the at least one bioactive agent until the degradation of the degradable plug" as claimed. Rather the delivery matrix 27 of Brown, whether degradable or not, inherently permits drug elution through the matrix 27 and out of the pores regardless of the state of the matrix 27.

Similarly, the Examiner's citation to membrane 34 fails to support the rejection under 35 U.S.C. §102(e). As clearly stated at Col. 9, lines 10-16, the membrane 34 "allows the active agent to diffuse through the membrane to the desired predetermined location." Brown completely fails to disclose, either expressly or by implication, that the membrane 34 is either degradable or is a plug "to prohibit release of the at least one bioactive agent until the degradation of the degradable plug" as claimed.

Accordingly, in the absence of a proper anticipation rejection under 35 U.S.C. §102(e), the rejection of Claim 20 based upon Brown must be reversed, independently of the disposition of Claim 16 from which it depends.

Patentability of Claims 26-27 Substantially Rests With Patentability of Independent Claim 16

While the specifically claimed elements in each of Claims 26 and 27 are broader than the specific disclosure in the Brown Reference, Applicants acknowledge that if any element of a Markush claim, which format Claims 26 and 27 are framed in, is anticipated the entire claim is considered anticipated. *Ecolochem, Inc. v. Southern California Edison Co.*, 91 F.3d 169 (Fed. Cir. 1996) and *In re Skoll,* 523 F.2d 1392, 1397, 187 USPQ 481, 484-85 (CCPA 1975). Thus, patentability of Claims 26 and 27 is asserted based upon the patentability of independent claim 16, discussed above.

Claim 27: Brown Fails to Teach Discontinuous Independent Internal Cavities

The Examiner asserts that Brown discloses void space 20 or channel in Fig. 12 which comprises a plurality of independent internal cavities along the length of the structural member, arguing that the cavity 20 may be intermittent referencing Col. 5, lines 52-55. The cited section of the reference does not support the anticipation rejection of Claim 27. Contrary to the Examiner's assertion, the disclosure found at Col. 5, lines 52-55 merely states that the cavity 20 "need not extend the entire length of the elongated or tubular member 12." This teaching merely stands for what it states, i.e., that the cavity may be shorter than the entire length of the tubular member 12. It does not expressly or impliedly teach that the cavity 20 may comprise a *plurality* of *independent internal cavities* as affirmatively claimed in Claim 27.

Arguably, Figures 13-17, and the associated disclosure at Col. 12, line 1 through Col. 13, line 43, suggest that there may be discontinuous cavities in a stent, i.e., those formed by formation of slots 108 intersecting and "dividing" a single helical groove 120 already loaded with the active agent 123 into discontinuous groove sections 120, Applicant has asserted, and maintains its assertion that a groove 20 or 120 is not an internal cavity as claimed, and the process of forming slots 108, which it segregates the single helical groove 120 into groove portions, those groove portions are not "along the length of the structural elements" as recited in Claim 27.

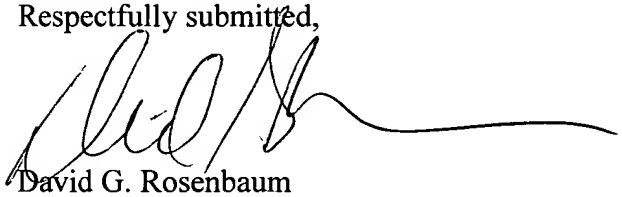
Accordingly, the Examiner's rejection of Claim 27 as being anticipated by Brown under 35 U.S.C. §102(e) is improper and should be reversed, independently of the disposition of base independent claim 16.

Summary

The pending and rejected Claims 16, 20 and 26-28 are directed to a specific embodiment of the invention described in the specification as originally filed at Page 8, lines 8-13. Base Claim 16 affirmatively recites a structure having two layers, i.e., a base layer and a second layer covering the base layer, with a void space intermediate the base layer and the second layer. Focusing on the claim language "first region" and "second region," the Examiner has apparently overlooked that the first region is further defined as comprising a base layer and that the second region is further defined as comprising the second layer. In choosing to selectively dissect and reconstruct the sole reference relied upon in making the final rejection, Examiner Miller has recast the Brown reference in a light unsupported by the express constraints of the reference itself.

An anticipation rejection under 35 U.S.C. §102(e) requires that there be identity between the claim elements and the reference. Such identity is unequivocally not present between the elements of the rejected claims and the Brown reference. In the absence of such identity, the Board is compelled to reverse the Examiner's rejection and allow Claims 16, 20 and 26-28, which reversal is respectfully solicited.

Respectfully submitted,



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Claims Appendix

The following is a listing of the claims on appeal.

Claim 16. An endoluminal stent for delivering a bioactive agent to a situs in a body, comprising:

a plurality of structural elements forming a radially expandable cylindrical member, the plurality of structural elements having a wall thickness; wherein the structural elements are fabricated of a metal and comprised of a first region comprising a base layer and a second region comprising a second layer covering the base layer, the second region further comprising a layer of void space intermediate the base and second layers and enclosed therebetween;

a plurality of pores passing through at least one of the base and second layers and communicating with the void space; and

at least one bioactive agent retained within the void space and elutable through the plurality of pores.

Claim 20. The endoluminal stent according to claim 16, further comprising a degradable plug residing within the plurality of pores to prohibit release of the at least one bioactive agent until the degradation of the degradable plug.

Claim 26. The endoluminal stent according to claim 16, wherein the metal is selected from the group consisting of titanium, vanadium, aluminum, nickel, tantalum, zirconium, chromium, silver, gold, silicon, magnesium, niobium, scandium, platinum, cobalt, palladium, manganese, molybdenum and alloys thereof, including zirconium-titanium-tantalum alloys, nitinol, and stainless steel.

Claim 27. The endoluminal stent according to claim 16, wherein the bioactive agent further comprises a pharmacologically active agent selected from the group consisting of antibiotic drugs, antiviral drugs, neoplastic agents, steroids, fibronectin, anti-clotting drugs, anti-platelet function drugs, drugs which prevent smooth muscle cell growth on inner surface wall of vessel, heparin, heparin fragments, aspirin, coumadin, tissue plasminogen activator, urokinase, hirudin, streptokinase, antiproliferatives,

methotrexate, cisplatin, fluorouracil, adriamycin, antioxidants, ascorbic acid, beta carotene, vitamin E, antimetabolites, thromboxane inhibitors, non-steroidal and steroidal anti-inflammatory drugs, immunosuppresents, such as rapomycin, beta and calcium channel blockers, genetic materials including DNA and RNA fragments, complete expression genes, antibodies, lymphokines, growth factors, vascular endothelial growth factor and fibroblast growth factor, prostaglandins, leukotrienes, laminin, elastin, collagen, nitric oxide, and integrins.

Claim 28. The endoluminal stent according to claim 16, wherein the void space comprises a plurality of independent internal cavities along the length of the structural elements.